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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,190	06/24/2003	Maria Elena Garcia Armenta	222992	1009

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EXAMINER

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/602,190

Applicant(s)

GARCIA ARMENTA ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 7 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

### ***Claim Rejections 35 U.S.C. 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 4, and 6 recite “sodium glicolate” “magnesium estearate”. Those phrases are not found in the prior art and the specification provides no definition as to the scope of those phrases. The claims are indefinite as to the compounds defined by those phrases. Those phrases appear to be typographic errors of “sodium glycolate” and “magnesium stearate.” Therefore, for the purpose of examination, those phrases are treated as “sodium glycolate” and “magnesium stearate.”

Claims 1 and 6 recite “and other recipients if necessary.” However, the application or the claims provide no further guidance as to the conditions for “if necessary” and what are the “other recipients.” The claims are indefinite as to the scope of “other excipients if necessary.”

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4. Claims 3-4, and 6 recite the limitation "ketorolac tromethamine" and "tramadol hydrochloride" in lines 2-4. There is insufficient antecedent basis for this limitation in the claim.
5. Claim 6 recites the limitation "sodium glycolate starch" and magnesium stearate" in line 7. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections 35 U.S.C. 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raffa et al. (EP 0 546 676) and Mauskop (U.S. 5,914,129), and in further view of Saslawski et al. (US 6,372,255), and Physicians' Desk Reference.
8. Raffa et al. teaches a pharmaceutical composition comprising a tramadol compound and a non-steroid anti-inflammatory drug (NSAID), and the method of using the same for treating pain. The composition provides benefits, such as less opioid side effects and synergistic pharmacological effects. See the abstract. Tramadol compounds may be any salts of tramadol, such as hydrochloride salt. See, particularly, page 3, lines 26-34. Any of the well-known NSAID may be used in the composition. The ratio of tramadol to NSAID is in the range of 1:1 to 1:200. The composition may be prepared according to conventional pharmaceutical compounding techniques. Known pharmaceutical carrier and other excipients may be used in the composition and the composition may be in the any of the known dosage forms, such as powders, capsules, etc. See, particularly, page 3, line 50 to page 4, line 49. Mauskop also disclosed a pharmaceutical

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composition for treating pain comprising an opioid analgesic agent and a non-opioid agent, wherein tramadol is expressly taught as one of the preferred opioid agent and ketorolac as one of the preferred non-opioid agents. See, particularly the claims.

9. The primary references do not teach expressly the particular carrier and excipients recited herein, or the particular salts of tramadol and ketorolac, or the amounts of each of the ingredients in the composition.

10. However, Saslawski et al. teaches that the particular carrier and excipients herein are well-known pharmaceutical carrier and excipients. See, particularly, column 5, line 37 to column 6, line 67. Further, Physicians' Desk Reference reveals that tramadol chloride and ketorolac tromethamine are the known salt currently employed clinically for tramadol and ketorolac.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a pharmaceutical composition for treating pain comprising ketorolac tromethamine and tramadol hydrochloride as herein recited. A person of ordinary skill in the art would have been motivated to make a pharmaceutical composition for treating pain comprising ketorolac tromethamine and tramadol hydrochloride as herein recited because tramadol and ketorolac are known to be used together and to provide benefit such as less opioid side effects and pharmacological synergistic effects, and ketorolac tromethamine and tramadol hydrochloride are the particularly salts used clinically. Note the optimization of a result effective parameter, e.g., the amount of therapeutical agents, or the amounts of the well-known pharmaceutical excipients, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215. Further note that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the

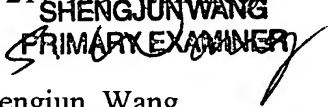
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optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). As to claim 6, note a method of making a composition by merely mixing or combining ingredients is considered prima facie obvious. Analyzing the content of a pharmaceutical composition for assuring the quality would have been within the purview of ordinary skill in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
SHENGJUN WANG  
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Art Unit 1617